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Changing LBC suppliers in a High Volume Laboratory: Improving Quality and Efficiency

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Overview

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Derby converted to ThinPrep™ in December 2013

- Why?
- How?
- Impact on screening and reporting
- Lessons learned
  - What went well
  - What not so well
- Performance Indicators

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Where is Derby?

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Background - workload

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- Derby cytology laboratory is one of largest screening centres in the UK – will be processing 170,000+ LBC samples in 2016/17

- High workload created from merger of four laboratories across Derbyshire and Nottinghamshire in 2010/11

- Initial merged workload of 170,000 fell with implementation of HPV Triage and Test of Cure in September 2012:
  - 2011/12 – 159,989
  - 2012/13 – 155,571
  - 2013/14 – 141,198
  - 2014/15 – 135,048
  - 2015/16 – 136,415

  - Successful tender bid added 36,000 Lincolnshire samples from 1st April 2016, making ~172,000 p.a.

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Background - LBC technology

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- Derby used SurePath™ since UK LBC implementation in 2005/06
- All of East Midlands used SurePath under ‘umbrella’ contract
- Initial 5 year contract
- Contract re-negotiated locally in 2010/11 for merged workload
- Rolled over for 2 years, due for renewal in 2012/13

- BUT, other things happening at the same time:
- Cytology service provision being looked at across a bigger area as part of a wider Pathology services review
- Cytology remit to incorporate future plans for HPV primary screening
- Needed to find most suitable system for centralised LBC processing and HPV testing on combined workload of potential new area

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Proposed new area (PL+) – ‘North’ East Midlands

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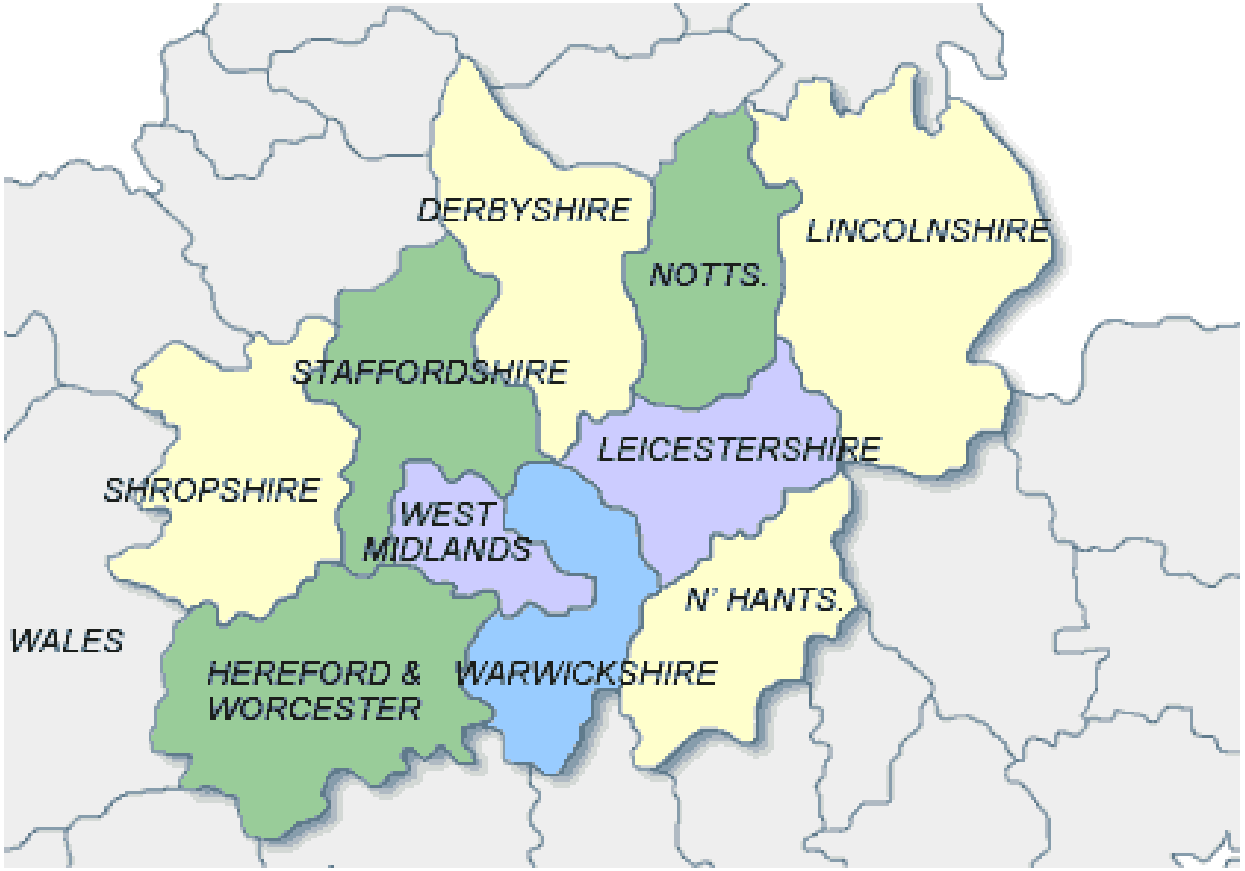

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Cytology Project Group

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- Cytology clinical delivery group established across proposed new area
- **Future strategic direction** = to perform HPV primary screening and associated cytology reporting, most likely on one site

- **Current task – to work up a model to centralise all LBC prep and HPV testing onto one site**

  Q: Could any one site currently do this?

  A: Not while using different LBC technologies

- **Option appraisal undertaken**
  - To compare the advantages and disadvantages of both LBC technologies, considering clinical, quality and cost elements
  - To determine the single most efficient system for centralised Cytology sample processing and HPV testing, now and future

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Benefits of change

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- Ease of processing large volumes of work – ThinPrep processing is fully automated, ideal for high throughput of work in a single high volume laboratory
- ThinPrep has integral chain of custody / sample identification – less risk in a centralised processing set-up
- Provides single platform for future HPV testing
- Cost per test increase avoided - costs taken from NHS supply chain national framework
- Added benefit of a regional price reduction for all because southern half of the region were already all ThinPrep users

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Risks of change

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- Re-training of sample takers and laboratory staff required
- Risk of breaching TAT targets during transition phase due to decreased screening capacity whilst screening staff undergo training
- Processing both LBC technologies during transition phase
- ? Increased inadequate rate – commissioners and sample takers were concerned - perception that TP has significantly higher inadequate rate than SP
- But benefits outweighed risks → conversion

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The conversion process

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- Timescale short - out of contract with current provider
- Phased conversion planned – Derby by Jan 2014, Lincoln April 2014
- Conversion training needed for:
  - **Screening staff** – interpretation of ThinPrep samples
  - **Sample takers** – new technique
  - **Laboratory support staff** – use of new processing equipment & staining machines

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T5000 autoloaders x2

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T5000 autoloaders x3

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Prep lab

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Conversion Timeline

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- Start to finish = 3 months!
- 35 cytologists converted
- ~3000 sample takers, including 9 acute Trusts (Colp, Gynae, GUM)
- Lab re-fitted
- New equipment installed – T5000 autoloaders and staining machines
- Year 2 of HPV Triage and Test of Cure testing started in middle of it all – number of HPV tests quadrupled
- We did it – but was it all plain sailing?.....

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Conversion Issues

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- Do not under-estimate **time for sample taker training**
- Ensuring all practices and clinics pump-primed with new kits
- Ensuring all practices and clinics remove old kits
  - What to do with old kits? - sufficient for 40,000 tests!
- Insufficient time for prep staff to train on T5s
- Running SP processing at same time
- Vial storage – problem with the processing backlog that developed

- But none of these were show stoppers
- Hologic provided invaluable support in all areas

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Impact of conversion on screening and reporting

- Turn Around Time (TAT)
- Screener confidence & productivity
- Sample quality and morphology
- Inadequate rate & high-grade detection rate

TAT

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- **TAT increased but not all to do with conversion**

- December – ‘quiet month’ - thought good time to convert
- But conversion lasted into January when workload rocketed
  …….and stayed that way until August in 2014
- Reduced screening productivity during conversion, but also
- Reduced screening capacity
  - Cytoscreener left
  - Maternity leave x2
  - retirement
- Locum (agency) screeners were needed to achieve 14 day TAT

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Screener confidence/productivity

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- Conversion = 1 day course, 100 slides
- Only 2/35 required to do additional 100 slide consolidation set
- But would 200 slides have been be better for all?
  - Many screeners said would have preferred this
  - Lacked confidence after 100 slides, more microscopy practice wanted
  - New NHSCSP conversion guidance is now 200 slides with both sensitivity and specificity calculated on these 200 slides

- Pressure on checkers
  - Checking doubled in first month, but no more experienced than screeners – *an issue with whole lab conversions* - no TP experience, as would have with an individual converting

- Multi-header sessions essential – Hologic on-site
- Additional Cytology Training Centre sessions on-site - very helpful

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Sample quality & Morphology changes

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- Staining
  - training sets variable quality
  - different appearance to adjust to – newer screeners never seen orange!
- Reactive endocervical cells caused few problems to start with
  - some overcalling in early days
- Blood-stained and scanty samples
  - Gaps, spaces and blood
  - adequate / inadequate decisions caused problems
- **But cells are cells – you soon get used to what you're looking at!**
  - Dyskaryosis is dyskaryosis
  - Metaplastics are metaplastics, etc, etc……

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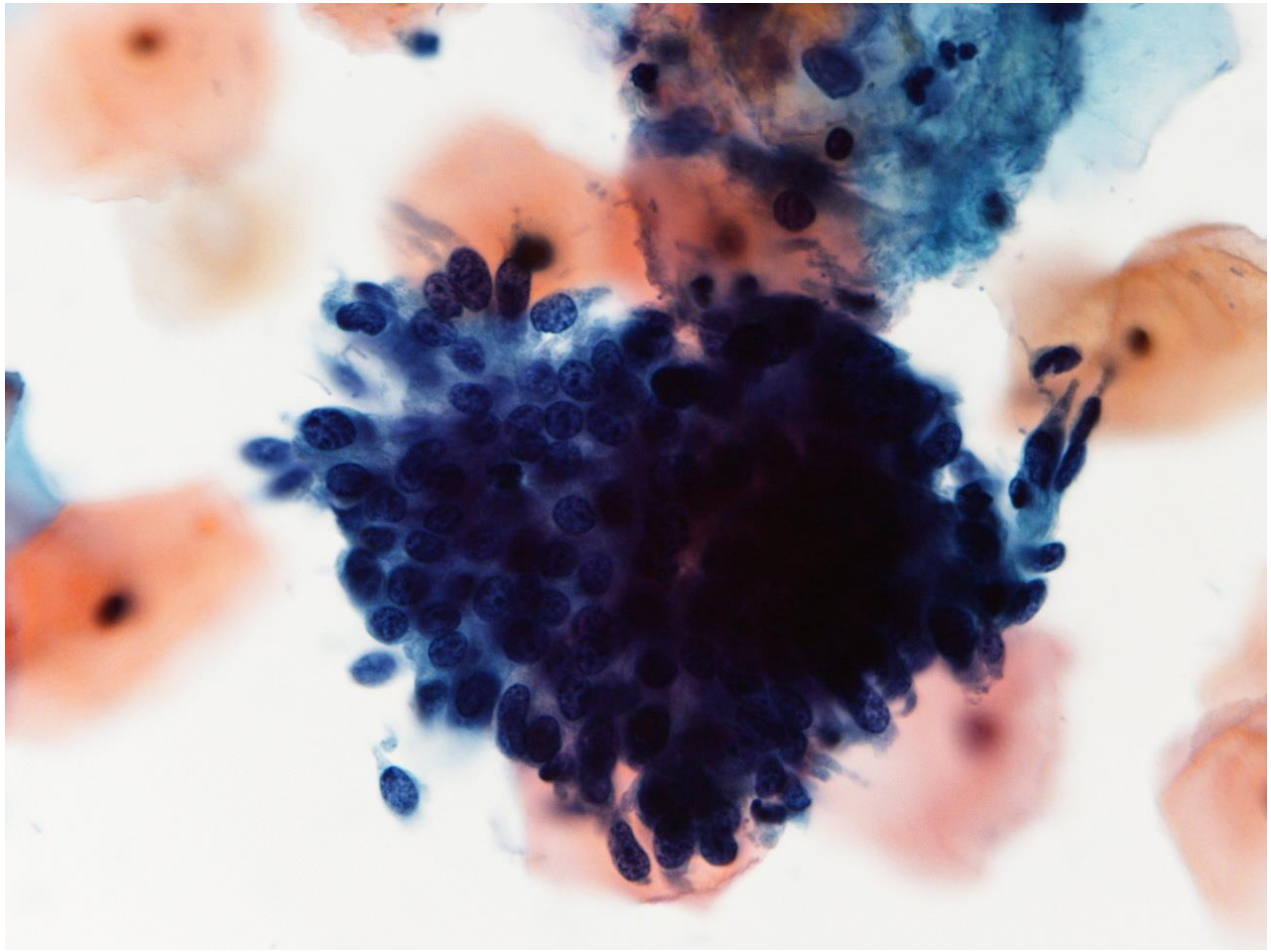
CGIN is CGIN



- **Key Performance Indicators**

Inadequate rate

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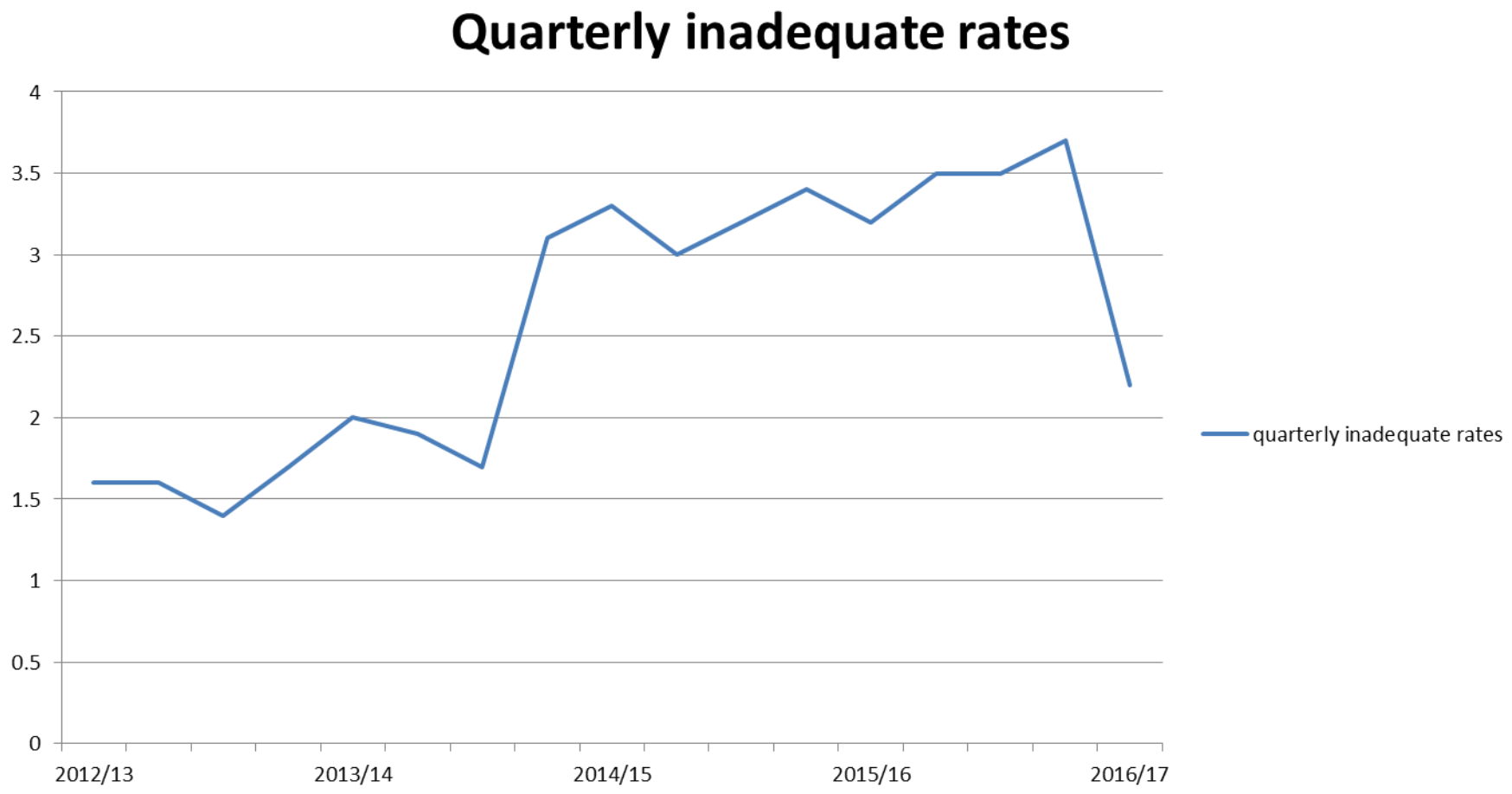

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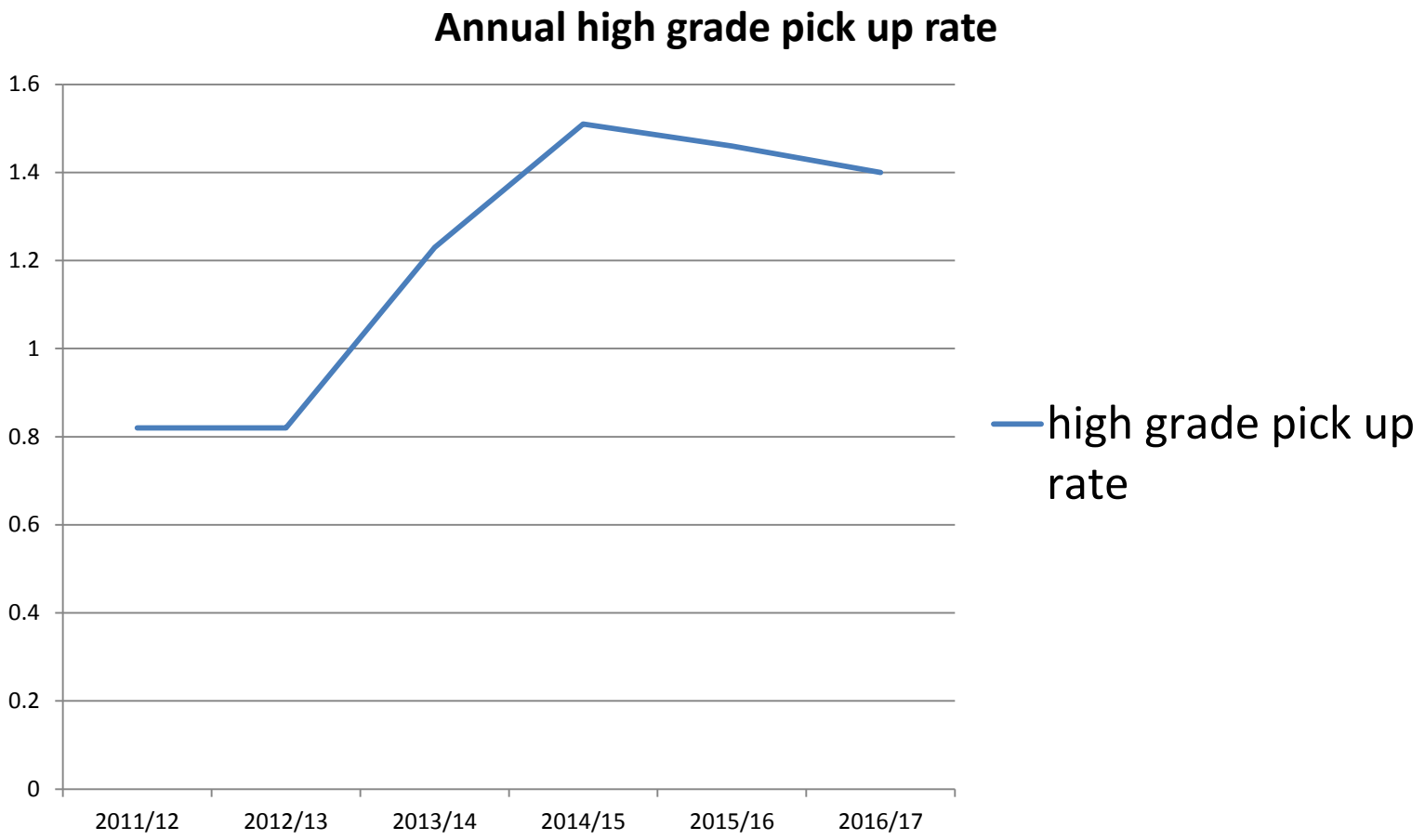
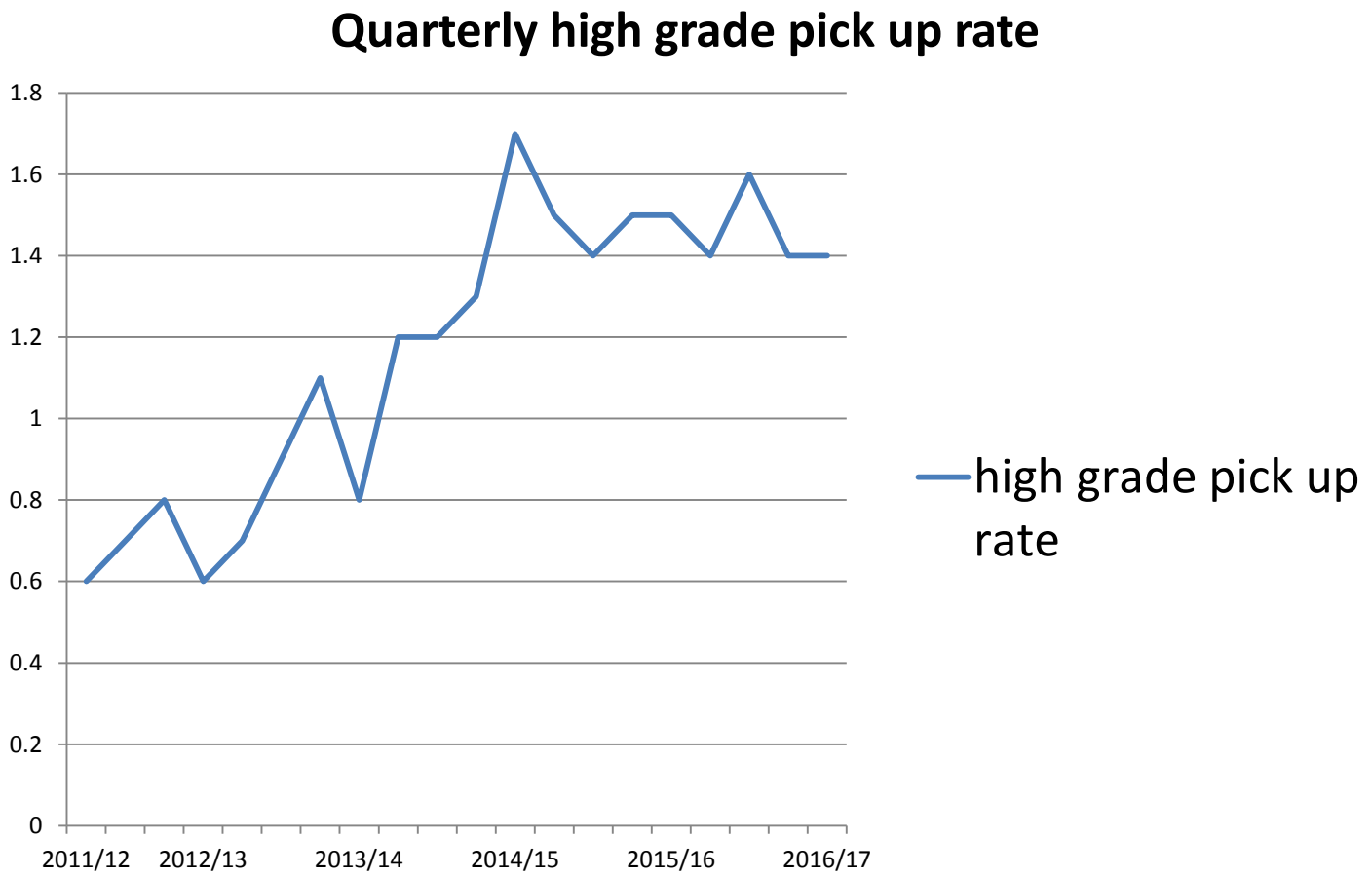
HG pick-up rate – almost doubled



High grade pick-up rates



High Grade increase, not due to overcalling – see PPV

YEAR	HG	PPV
2011/12	0.82	91.6
2012/13	0.82	93.9
2013/14	1.23	95.0
2014/15	1.51	92.6
2015/16	1.46	88.3
2016/17	1.32	

Key Performance Indicators
5 year trends

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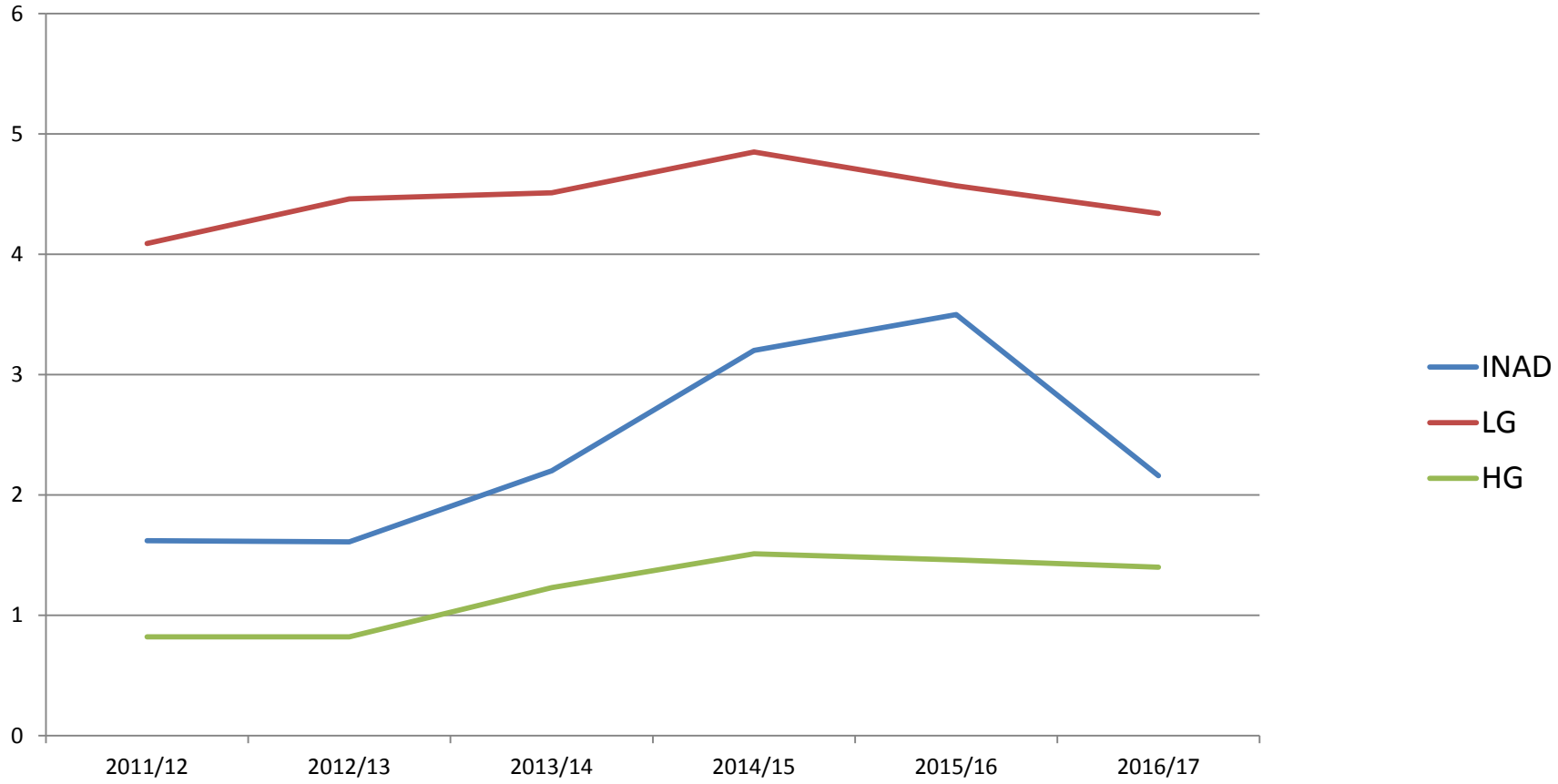

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Reasons for increased HG rate

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- HG changes not seen/misinterpreted/undercalled in SP?
- Implementation of HPV Triage at same time – any effect on reporting profile?
- Use of ‘Borderline can’t exclude HG’ category stopped
- Just the fact that all staff undertaken intensive training?
- No definite answers - data currently being analysed for publication

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High Grade reporting rates (%)

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year	borderline	LG dysk	moderate	severe	?invasive	?gld neopl
2011/12	3.4	0.7	0.2	0.6	0.0	0.0
2012/13	3.7	0.8	0.2	0.6	0.0	0.0
2013/14	2.2	2.3	0.3	0.8	0.0	0.1
2014/15	2.6	2.3	0.6	0.8	0.0	0.0
2015/16	2.3	2.2	0.6	0.8	0.0	0.0
2016/17	2.2	2.3	0.6	0.7	0.1	0.1

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Reducing the inadequate rate - scanty samples

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- Gaps and spaces in preps took some getting used to
- Screeners found adequacy difficult to judge in early days
- No national adequacy guidelines
- Cell count of 6 per high power field used, but not so rigidly now
  - *Common sense must prevail – assess atrophy, presence of TZ, etc*
- Hologic on-site support helped enormously
- Developed algorithm for scanty samples:

  Is blood present?

  Yes – have acid treated

  No – *do not* have acid treated, *do count*

  <6 = inadequate; > 6 = adequate

- **Adequacy must be decided cytologically NOT just by a cell count**

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Reducing the inadequate rate - blood stained samples

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- Caused confusion initially - what to treat?
  - Some screeners put all scanty samples for treat, blood or no blood
  - Some screeners put all bloody samples for treat, even if cellular
- Only blood stained samples benefit from acid treatment
- Acid treatment is time consuming so try to limit what is treated
  - *Could we have been more well prepared for this aspect of screening?*

- Initially much improved but slipped over time
- Checkers and APs looked at all Inads and Treats for a month
- Rule of thumb:
  - if it's scanty and bloody – treat it
  - If it's scanty but no blood – it's scanty!

    - *decide if inadequate based on cytology & use count as last resort*

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- Now back to the conversion

Objective achieved?

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Original option appraisal:

- To provide most efficient system for centralised processing and HPV testing
- Recommendation = conversion to ThinPrep™

- **Yes, objective achieved – successfully converted**
- Much more efficient, streamlined processing lab
- No processing delays whilst awaiting samples being booked in on computer
- Added value for women = ↑ detection of high grade disease

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Financial impact

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Costs

- Pump priming of sample taker kits
  - Offset by selling old kits!
- Stains – not previously required as integral to SP system

Savings

- 2 WTE lab support staff
  - 3 part-time staff not replaced as much less manual processing required with TP
- No additional staff required for increased volume of HPV testing
- Only additional data entry staff needed for additional work 2016
- No increase in cost per test to purchasers

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What went well

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- Timescale – amazing achievement!
- Phased conversion for screeners and sample takers - careful planning required
- Sample taker training, despite admin burden for lab

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What could have gone better – lessons learned

- More operator training pre ‘go-live’ date
- Get locum screeners in sooner to ‘mop up’ SP slides, don’t screen both technologies
- Staining – protocols should have been decided on beforehand
- More knowledge of acid treats / re-preps
- Excess kit management – SP and TP
- Screener conversion – more training slides required

Summary

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Conversion to ThinPrep™ means we now have a screening technology that meets current service needs but also provides flexibility to meet future screening needs more effectively and efficiently – whatever they may be?!

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